



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

09/940,545

08/29/2001

Lloyd Wolfenbarger JR.

58772.000004

5273

7590

08/13/2004

JENKINS AND GILCHRIST
1445 ROSS AVENUE, SUITE 3200
DALLAS, TX 75202

EXAMINER

COMSTOCK, DAVID C

ART UNIT

PAPER NUMBER

3732

DATE MAILED: 08/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/940,545

Applicant(s)

WOLFINBARGER ET AL.

Examiner

David Comstock

Art Unit

3732

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33 and 34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33 and 34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Allowable Subject Matter

The indicated allowability of claims 33 and 34 and the corresponding potential grounds for interference indicated in the paper mailed 13 January 2004 are withdrawn in view of the rejections set forth below.

Specification

The disclosure is objected to because of the following informalities: Page 18, line 2, "including those described in." should be deleted since it is unclear and incomplete.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical

Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim 34 is rejected under 35 U.S.C. 102(b) as being anticipated by Livesey et al. (5,336,616).

Livesey et al. disclose that it is known to contact bone for transplantation with glycerol, or other liquid organic preservation solution, and to freeze-dry (i.e. lyophilize) or cryopreserve the bone (see col. 3, lines 31-37 and 53-57). It is noted that "bone" is understood to refer to monolithic bone, i.e. whole bone or bone portions, as opposed to morselized or powdered bone, since there is nothing to indicate otherwise, since the disclosure refers to "transplantation" of the bone (id.), and since this is the plain sense of the word.

Claim 34 is rejected under 35 U.S.C. 102(e) as being anticipated by Boyce et al. (5,899,939).

Boyce et al. disclose a monolithic bone implant, i.e. whole bone or a portion of whole bone, 20 that is contacted with a liquid organic agent, i.e. a type of polyethylene glycol, and freeze-dried, i.e. lyophilized (see col. 1, lines 6-17; col. 2, lines 9-15; col. 4, lines 20-24 and 45-46; col. 4, line 53-65; col. 5, lines 21-29; and col. 6, lines 8-13, 45-46 and 51-52. It is noted that providing layers and demineralizing the implant are both optional; therefore, the scope of the disclosure includes mineralized bone that is not provided with the layers (id.).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Livesey et al. (5,336,616) in view of Morse (5,333,626).

Livesey et al. disclose the claimed invention except for explicitly disclosing packaging of the implant. Morse discloses a similar invention that is packaged to preserve sterility and biologic potential in the implant and to avoid contamination and infection in the patient (see Fig. 1 and col. 1, lines 6-18; col. 2, lines 21-26; col. 3, lines 10-12, 21, 31-50, 57-61; col. 4, lines 8-12; col. 5, lines 57-65; col. 6, lines 5-25 and 43-46; and col. 7, lines 40-47). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a bone implant as disclosed by Livesey et al. with packaging, in view of Morse, in order to preserve sterility and biologic potential of the bone implant and to avoid contamination and infection in the patient. It would have been further obvious to provide the glycerol or liquid organic preservation solution in any of numerous ranges of amounts, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Boyce et al. (5,899,939) in view of Morse (5,333,626).

Boyce et al. disclose the claimed invention except for explicitly disclosing packaging of the implant. Morse discloses a similar invention that is packaged to preserve sterility and biologic potential in the implant and to avoid contamination and infection in the patient (see Fig. 1 and col. 1, lines 6-18; col. 2, lines 21-26; col. 3, lines 10-12, 21, 31-50, 57-61; col. 4, lines 8-12; col. 5, lines 57-65; col. 6, lines 5-25 and 43-46; and col. 7, lines 40-47). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the bone implant as disclosed by Boyce et al. with packaging, in view of Morse, in order to preserve sterility and biologic potential of the bone implant and to avoid contamination and infection in the patient. It would have been further obvious to provide the liquid organic agent in any of numerous ranges of amounts, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Response to Arguments

Applicant's arguments with respect to Prewett (5,298,254) and Lyle (5,061,286) have been considered but are moot in view of the new ground(s) of rejection set forth above.

Conclusion

The prior art previously made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David C. Comstock whose telephone number is (703) 308-8514.



D. Comstock
02 August 2004



EDUARDO C. ROBERT
PRIMARY EXAMINER